



DT14 Rec'd PCT/PTO 102 OCT 2004

#4

Referenced
in
Box

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wenbin Dang

Application No.: 10/500,795

Int'l Filing Date: January 9, 2003

For: Compositions for Treatment of
Central Nervous System Neoplasms, and
Methods of Making and Using the Same

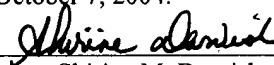
Examiner: Not yet assigned

Art Unit: Not yet assigned

Attorney Docket No.: GPT-030.01

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on October 7, 2004.


Shirine M. Darvish

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97 (b)(3)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the requirements of 37 C.F.R. 1.56 and 1.97(b)(3), submitted herewith on Form PTO-1449 is a list of publications identified in a communication from the United States Patent and Trademark Office issued in a related application. Applicants respectfully request that the Examiner consider the listed publications and indicate they were considered by making appropriate notations on the attached Form 1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that the cited documents are material or constitute

“prior art.” If the Examiner applies the listed documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute “prior art” under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the referenced documents be applied against the claims of the present application.


Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed publication dates should not be construed that the information in the cited documents was actually published or otherwise publicly available on the date indicated.

Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. However, the Commissioner is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Account, No. 06-1448, Reference GPT-030.01.**

Date: October 7, 2004

Customer No.: 29755
Patent Group
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210
617-832-1000
617-832-7000 (FAX)

Respectfully Submitted,



Theresa C. Kavanaugh
Reg. No. 50,356
Attorney for Applicants



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

| | |
|------------------------|-----------------|
| Application Number | 10/500,795 |
| Filing Date | January 9, 2003 |
| First Named Inventor | Dang |
| Art Unit | NYA |
| Examiner Name | NYA |
| Attorney Docket Number | GPT-030.01 |

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| | AA | US-4,638,045 | 01-20-1987 | Kohn, et al. | |
| | AB | US- 5,219,564 | 06-15-1993 | Zalipsky, et al. | |
| | AC | US- 5,099,060 | 03-24-1992 | Kohn, et al. | |
| | AD | US- 6,040,330 | 03-21-2000 | Hausheer, et al. | |
| | AE | US- 6,017,935 | 01-25-2000 | Mastalerz, et al. | |
| | AF | US- 6,002,023 | 12-14-1999 | Kingston, et al. | |
| | AG | US- 5,990,325 | 11-23-1999 | Holton, et al. | |
| | AH | US- 5,981,564 | 11-09-1999 | Page, et al. | |
| | AI | US- 5,977,164 | 11-02-1999 | Carver, et al. | |
| | AJ | US- 5,977,163 | 11-02-1999 | Lie, et al. | |
| | AK | US- 5,977,992 | 10-26-1999 | Carver, et al. | |
| | AL | US- 5,922,754 | 07-13-1999 | Burchett, et al. | |
| | AM | US- 5,919,815 | 07-06-1999 | Bradley, et al. | |
| | AN | US- 5,908,835 | 06-01-1999 | Bissery | |
| | AO | US- 5,912,263 | 06-15-1999 | Menichincheri, et al. | |
| | AP | US- 5,902,822 | 05-11-1999 | Golik, et al. | |
| | AQ | US- 5,877,205 | 03-02-1999 | Andersson | |
| | AR | US- 5,854,278 | 12-29-1998 | Pandey, et al. | |
| | AS | US- 5,840,929 | 11-24-1998 | Chen | |
| | AT | US- 5,821,363 | 10-13-1998 | Wicnienski, et al. | |
| | AU | US-5,817,840 | 10-06-1998 | Nicolaou, et al. | |
| | AV | US-5,808,888 | 09-15-1998 | Susnjara, et al. | |
| | AW | US-5,795,909 | 08-18-1998 | Shashoua, et al. | |
| | AX | US-5,780,653 | 07-14-1998 | Tao, et al. | |
| | AY | US-5,773,464 | 06-30-1998 | Walker, et al. | |
| | AZ | US-5,773,461 | 06-30-1998 | Wittman, et al. | |
| | BA | US-5,767,297 | 06-16-1998 | Mandai, et al. | |
| | BB | US-5,767,296 | 06-16-1998 | Terasawa, et al. | |
| | BC | US-5,760,072 | 06-02-1998 | De Bont, et al. | |
| | BD | US-5,756,776 | 05-26-1998 | Bombardelli, et al. | |
| | BE | US-5,750,691 | 05-12-1998 | Nicolaou, et al. | |
| | BF | US-5,739,359 | 04-14-1998 | Kingston, et al. | |
| | BG | US-5,728,687 | 03-17-1998 | Bissery | |
| | BH | US-5,719,177 | 02-17-1998 | Menichincheri, et al. | |
| | BI | US-5,693,666 | 12-02-1997 | Chen, et al. | |
| | BJ | US-5,688,977 | 11-18-1997 | Sisti, et al. | |
| | BK | US-5,686,623 | 11-11-1997 | Denis, et al. | |
| | BL | US-5,670,536 | 09-23-1997 | Durr, et al. | |
| | BM | US-5,614,645 | 03-25-1997 | Kingston, et al. | |
| | BN | US-5,608,087 | 03-04-1997 | Nicolaou, et al. | |
| | BO | US-5,597,931 | 01-28-1997 | Danishefsky, et al. | |
| | BP | US-5,908,835 | 06-01-1999 | Bissery | |
| | BQ | US-6,005,120 | 12-21-1999 | Holton, et al. | |
| | BR | US-5,424,073 | 06-13-1995 | Rahman, et al. | |
| | BS | US-5,547,981 | 08-20-1996 | Greenwald, et al. | |



PTO/SB/08b(08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

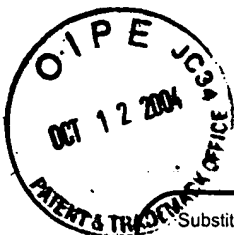
| | |
|------------------------|-----------------|
| Application Number | 10/500,795 |
| Filing Date | January 9, 2003 |
| First Named Inventor | Dang |
| Art Unit | NYA |
| Examiner Name | NYA |
| Attorney Docket Number | GPT-003.01 |

FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLA SS | Translation | |
|--|--------------------|--------------|----------|-------|--------------|-------------|----|
| | | | | | | YES | NO |
| | BT | WO 00/57852 | 10/05/00 | PCT | | | |
| | BU | WO 00/41678 | 07/20/00 | PCT | | | |
| | BV | WO 98/44021 | 10/08/98 | PCT | | | |
| | BW | WO 98/44020 | 10/08/98 | PCT | | | |
| | BX | WO 98/48859 | 11/05/98 | PCT | | | |
| | BY | WO 02/30472 | 04/18/02 | PCT | | | |
| | BZ | WO 02/03957 | 01/17/02 | PCT | | | |
| | CA | WO 03/007914 | 01/30/03 | PCT | | | |
| | CB | WO 03/007915 | 01/30/03 | PCT | | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | CC | Gutman, et al., "Targeted Drug Delivery for Brain Cancer Treatment," Journal of Controlled Release, 65:31-41 (2000). | |
| | CD | Harper, et al., "Enhanced Efficacy of a Novel Controlled Release Paclitaxel Formulation (PACLIMER Delivery System) for Local-Regional Therapy of Lung Cancer Tumor Nodules in Mice," Clinical Cancer Research, 5:4242-4248 (1999), XP-000900829. | |
| | CE | Wen, et al., "New Biodegradable Polymer for Drug Delivery System Poly(D,L-Lactide-coEthyl Ethylene Phosphage)," Proceed. Int'l. Symp. Control. Rel. Bioact. Mater. 27:664-665 (2000), XP-001094451. | |
| | CF | International Search Report for PCT/US03/00564. | |
| | CG | Betz, et al., "Blood-Brain-Cerebrospinal Fluid Barriers," Basic Neurochemistry: Molecular, Cellular and Medical Aspects, Chapter 32, 5 th Edition, Edited by G.J. Siegel, et al., Raven Press, Ltd., New York, 1994. | |
| | CH | Brem, et al., "Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas," The Lancet, Volume 345, April 22, 1995, p. 1008-1012. | |
| | CI | Cahan, et al., "Cytotoxicity of Taxol in Vitro Against Human and Rat Malignant Brain Tumors," Cancer Chemother Pharmacol. (1994) 33:441-444, Springer-Verlag. | |
| | CJ | Chamberlain, et al., "Salvage Chemotherapy With Paclitaxel for Recurrent Oligodendrogliomas," Journal of Clinical Oncology, Vol. 15, No. 12 (December): pp. 3427-3432, American Society of Clinical Oncology. | |
| | CK | Chamberlain, et al., "Salvage Chemotherapy With Taxol for Recurrent Anaplastic Astrocytomas," Journal of Neuro-Oncology. 43: 71-8, 1999, Kluwer Academic Publishers, Netherlands.. | |
| | CL | Choueka, Jack, et al., "Canine Bone Response to Tyrosine-Derived Polycarbonates and Poly (L-lactic acid)," Journal of Biomedical Materials Research, Vol. 31, 35-45 (1996), John Wiley & Sons, Inc. | |



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | |
|---|------------------------|--------------------------|-----------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/500,795 |
| | | Filing Date | January 9, 2003 |
| | | First Named Inventor | Dang |
| | | Art Unit | NYA |
| | | Examiner Name | NYA |
| Sheet 3 of 3 | Attorney Docket Number | GPT-003.01 | |

| | | |
|----|--|--|
| CM | Dordunoo, et al., "Taxol Encapsulation in Poly (ε-caprolactone) Microspheres," <i>Cancer Chemother Pharmacol</i> (1995) 36:279-282, Springer-Verlag. | |
| CN | Ertel, et al., "Evaluation of Poly (DTH carbonate), a Tyrosine-Derived Degradable Polymer, for Orthopedic Applications," <i>Journal of Biomedical Materials Research</i> , Vol. 29, 1337-1348 (1995), John Wiley & Sons, Inc. | |
| CO | Fountzilaz, et al., "Radiation and Concomitant Weekly Administration of Paclitaxel in Patients with Glioblastoma Multiforme. A Phase II Study," <i>Journal of Neuro-Oncology</i> , 45:159-165, 1999, Kluwer Academic Publishers, Netherlands. | |
| CP | Glanz, et al., "Weekly, Outpatient Paclitaxel and Concurrent Cranial Irradiation in Adults With Brain Tumors: Preliminary Results and Promising Directions," <i>Seminars in Oncology</i> , Vol. 22, No. 5, Suppl. 12 (October), 1995: pp.26-32, W.B. Sanders Company. | |
| CQ | Glantz, et al., "Paclitaxel Disposition in Plasma and Central Nervous Systems of Humans and Rats with Brain Tumors," <i>Journal of the National Cancer Institute</i> , Vol. 87, No. 14, July 19, 1995. | |
| CR | Gupta, et al. "Cytotoxicity and Cell-Cycle Effects of Paclitaxel When Used as a Single Agent and in Combination with Ionizing Radiation," <i>Int. J. Radiation Oncology Biol. Phys.</i> , Vol. 37, No. 4, pp. 885-895, 1997, Elsevier Science, Inc. | |
| CS | Hong, et al., "Taxol, Vincristine or Nocodazole Induces Lethality in G ₂ Checkpoint-Defective Human Astrocytoma U373MG Cells by Triggering Hyperploid Progression," <i>Carcinogenesis</i> , Vol. 20, No. 7, pp. 1161-1168, 1999, Oxford University Press. | |
| CT | Langer, et al., Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>Rev. Macromol. Chem. Phys.</i> , C23(1), 61-126 (1983), Marcel Dekker, Inc. | |
| CU | Leong, K. W., et al., "Polyanhydrides for Controlled Release of Bioactive Agents," <i>Biomaterials</i> , 1986, Vol. 7 September, Butterworth & Co. (Publishers) Ltd. | |
| CV | Prados, et al., "Phase II Study of Paclitaxel in Patients With Recurrent Malignant Glioma," <i>Journal of Clinical Oncology</i> , Vol. 14, No. 8 (August), 1996: pp. 2316-2321, American Society of Clinical Oncology. | |
| CW | Rosenthal, et al., "Phase II Study of Combination Taxol and Estramustine Phosphate in the Treatment of Recurrent Glioblastoma Multiforme," <i>Journal of Neuro-Oncology</i> , 47: 59-63, 2000, Kluwer Academic Publishers, Netherlands. | |
| CX | Sato, et al., "Pharmacokinetic Study of Taxol-Loaded Poly (lactic-co-glycolic acid) Microspheres Containing Isopropyl Myristate After Targeted Delivery to the Lung in Mice," <i>Biol. Pharm. Bull.</i> 19(12) 1596-1601 (1996), Vol. 19, No. 12, Pharmaceutical Society of Japan. | |
| CY | Suh, et al., "Regulation of Smooth Muscle Cell Proliferation Using Paclitaxel-Loaded Poly(ethylene oxide)-poly(lactide/glycolide) nanospheres," <i>J. Biomed. Mater. Res</i> , 42, 331-338, 1998, John Wiley & Sons, Inc. | |
| CZ | Walter, et al., "Intratumoral Chemotherapy," <i>Neurosurgery</i> , 37: 1129-1145, 1995. | |
| DA | Walter, et al., Interstitial Taxol Delivered From a Biodegradable Polymer Implant Against Experimental Malignant Glioma," <i>Cancer Research</i> 54, 2207-2212, April 15, 1994. | |
| DB | Wehbe, et al., "Histologic Evidence of a Radiosensitizing Effect of Taxol in Patients With Astrocytomas," <i>Journal of Neuro-Oncology</i> 39: 245-251, 1998, Kluwer Academic Publishers, Netherlands. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.